K003408

NOV 17 2000

GE Medical Systems

General Electric Company
PO Box 414, Milwaukee, WI 53201

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirement of 21 CFR Part 807.87(h).

Submitter: Larry A. Kroger, Ph.D.
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Summary prepared: October 5, 2000

PRODUCT IDENTIFICATION

Name: CT CardIQ Option 1.0

Classification Name: Accessory to a Computed Tomography System

Manufacturer: General Electric Medical Systems
16800 W. Ryerson Road
New Berlin, WI 53151

Distributor: Same as Manufacturer

Marketed Devices: CT CardIQ Option 1.0 contains features that are substantially equivalent to those of devices listed below:

Model:	LightSpeed™ QX/i 2.0
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K 000300
Model:	CT Coronary Artery Calcification Scoring (CACS)
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K 982004
Model:	Smart Vessel Analysis (SVA)
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K 993792
Model:	Advantage Windows (AW) Fusion
Manufacturer:	General Electric Medical Systems, Milwaukee, WI
510(k) #:	K 983256

K003408

DEVICE DESCRIPTION

CT CardIQ 1.0 is a software option with two subparts, CardIQ SnapShot Option and CardIQ Analysis Option. Each subpart can also be used as a stand-alone product. CardIQ SnapShot is an integrated cardiovascular image acquisition and reconstruction option for GE family of LightSpeed Multi slice CT scanners. It can be used to obtain prospective/retrospective EKG-gated CT images and anatomical images for CT angiography application. CardIQ Analysis is a post processing software that can be used in analysis of CT angiography images and for measurements of calcium deposits in coronary arteries.

Indications for Use:

CardIQ Snapshot is a hardware/software option for the GE family of multi-slice CT scanners. This product can be used to obtain EKG-gated anatomical images for CT angiography applications. EKG gating is used either retrospectively or prospectively during image acquisition and reconstruction process to minimize cardiac motion artifacts in CT images. CardIQ Analysis is a post processing software option for the Advantage Window Workstation (AW) platform. This product can be used for the analysis of CT angiography images and for the assessments of calcium deposits in coronary arteries. It provides a number of display, measurement, and batch filming features. The product can be used to aid trained physicians for visualizing and assessing cardiac anatomy and coronary vessels.

Comparison with Predicate:

CardIQ SnapShot is the hardware/software option of the CT CardIQ 1.0 for the GE family of multi-slice CT scanners. Features of this software package are substantially equivalent to those of following devices:

Device Name	FDA Clearance Number
LightSpeed™ QX/i 2.0	K 000300
CT Coronary Artery Calcification Scoring (CACS)	K 982004

CardIQ Analysis is a software post-processing option for the Advantage Workstation (AW) platform providing a number of display, measurement & batch filming/archiving features. This software package is substantially equivalent to the following devices:

Device Name	FDA Clearance Number
Smart Vessel Analysis (SVA)	K 993792
Advantage Windows (AW) Fusion	K 983256

CardIQ SnapShot and CardIQ Analysis individually or together do not affect the dosage characteristics or the imaging performance of the CT scanners.

Adverse Effects on Health:

Potential electrical, mechanical and radiation hazards are identified in a risk management summary (hazard analysis) and controlled by:

- System verification and validation to ensure performance to specifications, Federal Regulations, and user requirements.
- Adherence to industry and international standards. (UL/CSA and IEC).

CONCLUSIONS

The CT CardIQ Option 1.0 does not result in any new potential safety risks and performs as well as devices currently on the market. GE considers features of the CT CardIQ Option 1.0 to be equivalent to those of other marketed devices (references: LightSpeed™ QX/i 2.0 (K000300), CT Coronary Artery Calcification Scoring (K982004), Smart Vessel Analysis (K993792) and Advantage Window Fusion (K983256)).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 17 2000

GE Medical Systems
c/o Reiner Krumme
TUV Rheinland of North America
12 Commerce Road
Newtown, CT 06470

Re: K003408
CT Cord IQ Option 1.0.
Dated: October 30, 2000
Received: November 2, 2000
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Krumme:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INTENDED USE

510(k) Number (if known): _____

Device Name: CT CardIQ Option 1.0

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ -OR- Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K063408